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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/056,103

01/23/2002

Lydia L. Sohn

PRINP002

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01/05/2006

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EXAMINER

DOLE, TIMOTHY J

ART UNIT

PAPER NUMBER

2858

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

W.A

**Office Action Summary**

Application No.

10/056,103

Applicant(s)

SOHN ET AL.

Examiner

Timothy J. Dole

Art Unit

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 11-20, 22-35, 37 and 38 is/are pending in the application.

4a) Of the above claim(s) 38 is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-7, 11-20, 22-35 and 37 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claim 38 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method of making, there being no allowable generic or linking claim. Election was made **without** traverse in paper number 7.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (US 5,376,878).

Referring to claim 3, Fischer discloses a device for sensing and characterizing particles by the Coulter principle, said apparatus comprising: a conduit (fig. 1 (12)) through which a liquid suspension of particles (fig. 1 (26)) to be sensed and characterized can be made to pass, wherein said conduit has an effective electrical impedance which is changed with the passage of each particle therethrough (column 3, lines 61-67) and wherein the conduit has a cross-sectional area of less than about  $1\text{ }\mu\text{m}^2$  (column 7, lines 16-21) and a length, in the direction of passage of the particles, of between about .1 and about 50 micrometers (column 7, lines 16-21); a liquid handling-system for causing said liquid suspension of particles to pass through said conduit (column 7, lines 1-9); and a

measurement system for sensing the change of electrical impedance in said conduit  
(column 7, lines 9-14).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4-7, 11-19, 22, 24-29, 31-34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogg et al. (US 3,944,917) in view of Duffy et al. (IDS document number 4, "Rapid Prototyping of Microfluidic Systems in Poly(dimethylsiloxane)").

Referring to claims 1, 4, 11, 13, 14, 18, 22, 24, 25, 27, 29, 32 and 33, Hogg et al. discloses a device and method for sensing and characterizing particles by the Coulter principle, said apparatus comprising: a conduit (fig. 11 (99)) through which a liquid suspension of particles to be sensed and characterized can be made to pass (column 10, lines 34-37), wherein said conduit has an effective electrical impedance which is changed with the passage of each particle therethrough (column 10, lines 38-40); a liquid handling-system for causing said liquid suspension of particles to pass through said conduit (abstract and fig. 11); and a measurement system for sensing the change of electrical impedance in said conduit (column 10, lines 40-67), wherein the measurement system comprises a four-point electrode system having two inner electrodes (fig. 11 (102))

and (103)) and two outer electrodes (fig. 11 (101) and (104)), wherein the inner electrodes are positioned external to the conduit (fig. 11).

Hogg et al. does not disclose the conduit is formed at least in part from poly(dimethylsiloxane), and has a cross-sectional area of less than about  $1\text{ }\mu\text{m}^2$  and a length of less than about  $10\text{ }\mu\text{m}$ .

Duffy et al. discloses a microscale total analysis system wherein the conduit is formed at least in part from poly(dimethylsiloxane) (page 4974, column 1, lines 1-4), and has a cross-sectional area of less than about  $1\text{ }\mu\text{m}^2$  and a length of less than about  $10\text{ }\mu\text{m}$  (page 4974, column 2, lines 11-17). It should also be noted that according to MPEP 2144.04 (IV) (A), changing the size of a device does not render it patentable over the prior art unless there is a new or unexpected result. Since a very small particle is to be sensed, a corresponding device size would not lead to new or unexpected results, and therefore the device would not be patentably distinct over the prior art of record.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the conduit of Duffy et al. into the device and method of Hogg et al. for the purpose of providing a more sensitive and portable device (page 4974, column 2, lines 3-10).

Referring to claims 2 and 12, Hogg et al. discloses the device as claimed wherein said liquid handling-system comprises two reservoirs (fig. 11 (94) and (96)) linked by said conduit (fig. 11).

Referring to claims 5, 15, 26 and 31, Hogg et al. discloses the device and method as claimed, except for a microfluidics or nanofluidics system for delivering the liquid suspension of particles to the liquid handling system.

Duffy et al. discloses a microfluidics or nanofluidics system for delivering the liquid suspension of particles to the liquid handling system (page 4974, column 2, lines 11-22).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the microfluidics system of Duffy et al. into the device and method of Hogg et al. for the same purpose as given in claim 1, above.

Referring to claims 6, 7, 16 and 17, Fischer discloses the device as claimed except wherein the surface of the conduit and reservoirs has been functionalized to reduce or enhance adsorption of the particles to said surface.

Duffy et al. discloses the surface of the conduit and reservoirs have been functionalized to reduce or enhance adsorption of the particles to said surface (page 4976, column 1, third paragraph).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the functionalization of Duffy et al. into the device and method of Hogg et al. for the purpose of enhancing electroosmotic pumping (page 4976, column 1, third paragraph).

Referring to claims 19 and 34, Hogg et al. discloses the device and method as claimed wherein the device is substantially transparent (fig. 11 (93) and (98)). It should

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be noted that according to MPEP 608.02 (IX), the hatching of the device and the partition causing the aperture shows that the material that is used is transparent.

Referring to claims 28 and 37, Hogg et al. discloses the method as claimed wherein the sensing of the approach of particles to, the presence and characteristics of particles passing through, or the departure of particles from, said conduit, initiates additional measurements or actions on said particles (column 10, line 64 – column 11, line 14).

6. Claims 20 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogg et al. in view of Duffy et al. as applied to claim 11, 19, 29 and 34 above, and further in view of Metha (US 6,426,615).

Referring to claims 20 and 35, Hogg et al. as modified discloses the device and method as claimed except wherein the device further comprises an optical detection system.

Metha discloses an apparatus for analyzing particles comprising an optical detection system (column 9, lines 18-20).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the optical detection system of Metha into the device and method of Hogg et al. as modified for the purpose of visually determining sample flow whereby adding redundancy to the device.

7. Claims 23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogg et al. in view of Duffy et al. as applied to claims 22 and 29 above, and further in view of Curby (US 3,919,050).

Referring to claims 23 and 30, Hogg et al. as modified discloses the method as claimed except wherein the particle's residence time in the conduit is also measured.

Curby discloses a microparticle analysis system wherein the particle's residence time in the conduit is also measured (column 2, lines 42-48).

Therefore, it would have been obvious to one skilled in the art at the time of the invention to incorporate the residence time of Curby into the method of Hogg et al. as modified for the purpose of providing a more in depth analysis of particles under test. (column 2, lines 42-48).

#### *Response to Arguments*

8. Applicant's arguments with respect to claims 1-7, 11-20, 22-35 and 37 have been considered but are moot in view of the new ground(s) of rejection.

#### *Final Rejection*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

*Conclusion*

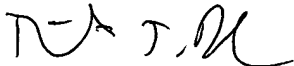
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Dole whose telephone number is (571) 272-2229.

The examiner can normally be reached on Mon. thru Fri. from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diane Lee can be reached on (571) 272-2399. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TJD



**DIANE LEE**  
SUPERVISORY PATENT EXAMINER